

**REMARKS/ARGUMENTS**

The foregoing amendments in the specification and claims are of formal nature, and do not add new matter.

Prior to the present amendment, Claims 1-48 were pending in this application, with Claim 15, 17-40 and 44-48 withdrawn from consideration. With this amendment, Claims 1-14, 16, and 41-42 have been canceled without prejudice, and Claims 49-65 have been added. Claims 49-65 are pending after entry of the instant amendment. The amendments to the specification and claims are fully supported by the specification and claims as filed and do not constitute new matter. The specification has been amended to simply add the sequence identifiers as requested by the Examiner. Applicants expressly reserve the right to pursue any canceled matter in subsequent continuation, divisional or continuation-in-part applications.

**I. Sequence Listing**

The Examiner alleges that the application fails to comply with the requirements of 37 C.F.R. 1.825 because sequence identifiers are missing from the Brief Descriptions of Figures 4 and 5 and from page 22, line 12 and page 29, line 9.

Applicants have amended the specification by adding the indicated sequence identifier to Figures 4 and 5 and page 22, line 12 and page 29, line 9. Submitted herewith is a paper copy of a revised sequence listing replacing the previous one. Also enclosed herewith are the computer readable form of a revised Sequence Listing, as well as a Sequence Submission Statement

**II. Objection to the Specification**

The specification is objected to because there appears to be two Brief Descriptions of the Figures.

Applicants have amended the specification by deleting the figure descriptions at pages 16-17 to avoid the duplication. The rejection is thereby rendered moot.

**III. Objection to the Claims**

Claims 2-4 and 10 are objected to as being improper dependent form for failing to further limit the subject matter of a previous claim.

Claims 2-4 and 10 have been cancelled. Newly added dependent claims, for example, Claims 53, 54 and 59, all further limit the claims to which they depend and comply with 37 C.F.R. 1.175 (c). The Objection is therefore rendered moot.

Claims 14, 16 and 41 are objected to allegedly due to minor informality.

Claims 14, 16, and 41 have been cancelled. The cancellation renders the objection moot. None of the newly added claims have the informality alleged by the PTO. The PTO is thereby requested to reconsider and withdraw the objection of Claims 14, 16 and 41.

#### **IV. Claim Rejections Under 35 U.S.C. § 112, First Paragraph**

##### **A. New Matter**

Claim 8 is rejected under 35 U.S.C. § 112, First Paragraph, as failing to comply with the written description requirement, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. In particular, the PTO alleges that the phrase "the purified and isolated nucleic acid of claim 1 ... luminesces toxins." allegedly because there is no support for SEQ ID NO:1 or any of its parts, being any of the listed toxins.

Without acceding to the PTO's rejection and solely for the purpose of advancing the prosecution of the instant application, Claim 8 has been cancelled. The cancellation renders the rejection to this claim moot. New Claim 57 recites "the isolated nucleic acid molecule of Claim 56, wherein the further nucleotide sequence encodes at least one of the *Bacillus delta endo* toxins, vegetative insecticidal proteins (vips), cholesterol oxidases, *Clostridium bifermentens* mosquitocidal toxins or *Photorhabdus luminescens* toxins." Claim 57 is well supported by the specification, for example, at page 4, lines 1-8. The PTO is therefore requested to reconsider and withdraw the rejection of Claim 8 and as it may apply to new Claim 57 under 35 U.S.C. § 112, First Paragraph.

##### **B. Written Description**

Claims 1, 9-14, 16 and 41 are rejected under 35 U.S.C. § 112, First Paragraph, as failing to comply with the written description requirement, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. In

particular, the PTO alleges that Applicants do not describe the homologs to SEQ ID NO:1 encompassed by the claims, and the structural and functional features that distinguish all such nucleic acids from other nucleic acid are not provided. For the reason outlined below, Applicants respectfully disagree.

Without acceding to the PTO's rejection and solely for the purpose of advancing the prosecution of the instant application, Claims 1, 9-14, 16 and 41 have been cancelled. The cancellation renders the rejection to these claims moot.

Applicants further submit that new Claim 50 is directed to a genus of nucleic acid molecule comprising a nucleic acid sequence having at least 70% sequence identity to SEQ ID NO: 1, wherein said nucleic acid molecule encodes a polypeptide that has the same insecticidal activity of a polypeptide encoded by SEQ ID NO:1. Claim 50 is well-supported by the specification as originally filed, for example, at page 8, lines 11-14, which states that, "A 'homolog' has at least one of the biological activities of the nucleic acid or polypeptide of the invention and comprises at least 50-70% identical amino acid or nucleic acid sequence thereto, preferably 75-85% and most preferably 90-95% identical amino acid or nucleic acid sequence thereto."

Applicants further submit that a skilled artisan would be able to identify a nucleic acid with 70% homology to SEQ ID NO:1, using standard scientific techniques for determining whether a nucleotide has 70% probability of being the same as the nucleotide by using techniques such as E-value of applications as BLASTN, FASTA, and BLASIP algorithms.

In addition, Claim 50 has specific functional limitation, as the encoded polypeptide of the claimed nucleic acid has the insecticidal activity of a polypeptide encoded by SEQ ID NO:1. Applicants submit that, coupled with the general knowledge available in the art at the time of the invention, the specification provides ample written support for such nucleic acid molecules at, for example, page 8, line 18 to page 9, line 2, and pages 23-26 of the specification. Thus, based on the high percentage of sequence identity and the described method of detecting and quantifying of the insecticidal activity of a polypeptide, one skilled in the art would have known at the time of the invention, that the Applicants had possession of the claimed nucleic acids. The PTO is therefore requested to reconsider and withdraw the rejection under under 35 U.S.C. § 112, First Paragraph, written description.

### **C. Enablement**

Claims 1, 9-14, 16 and 41 are rejected under 35 U.S.C. § 112, First Paragraph, as the specification does not provide reasonable enablement for nucleic acids that have 75% or 50% homology to SEQ ID NO: 1, a recombinant expression vector comprising the nucleic acid, and a plant/bacterium virus or fungus transformed within the nucleic acid. Therefore, the specification allegedly does not enable a person skilled in the art to make and/or use the invention commensurate in scope with these claims.

Without acceding to the PTO's rejection and solely for the purpose of advancing the prosecution of the instant application, Claims 1, 9-14, 16 and 41 have been cancelled. The cancellation renders the rejection to these claims moot.

Applicants further submit that new Claim 50 is directed to a genus of nucleic acid molecule comprising a nucleic acid sequence having at least 70% sequence identity to SEQ ID NO: 1, wherein said nucleic acid molecule encodes a polypeptide that has the same insecticidal activity of a polypeptide encoded by SEQ ID NO:1. As discussed under the above Written Description section, a skilled artisan would be able to identify a nucleic acid with 70% homology to SEQ ID NO:1, using standard molecular biology techniques.

In addition, new Claim 60 is directed to recite the recombinant expression vector containing the nucleic acid molecule of Claims 49, 50, or 51, and a host transformed with the vector expresses a polypeptide. Applicants submit that standard techniques and the methods for a recombinant expression vector producing a protein encoded by a nucleic acid and the transformation of a plant, bacterium, virus or fungus with the nucleic acid are described and referenced on pages 12-15 of the specification. One skilled in the art will be able to follow the cited protocols described within the specification in order to perform the claimed invention.

The PTO indicates that the specification fails to provide exact hybridisation/amplication techniques for isolating the nucleic acids that hybridise to SEQ ID NO: 1 or where to find the nucleic acids.

Applicants disagree with the characterization of the specification and submit that these techniques are well known in the art at the effective filing date of the present application, as evidenced by Sambrook et al., which discloses all common molecular biology techniques such as low stringency hybridisation, PCT protocols, etc. (the third edition of Molecular Cloning a laboratory manual Volumes 1-3; Sambrook and Russell Cold Spring Harbor Laboratory Press; Cold Spring Harbor, New York, ISB 0-87969-577-3).

The PTO also alleges that the specification fails to make insecticidal protein encoding nucleic acid with 75% or 50% homology to SEQ ID NO: 1. The PTO further alleges that the specification fails to provide guidance as to which amino acids of SEQ ID NOs: 2-4 can be altered.

New Claim 50 has specific functional limitation, such as, the encoded polypeptide of the claimed nucleic acid has insecticidal activity of a polypeptide encoded by SEQ ID NO:1. The specification, at pages 23-26, provides detailed protocol for detecting the insecticidal activities of a polypeptide or a nucleic acid. Therefore, a skilled artisan can readily determine whether a nucleic acid has 70% homology to SEQ ID NO:1 and whether this nucleic acid has the same insecticidal activity as the polypeptide encoded by SEQ ID NO:1. The PTO is therefore requested to reconsider and withdraw the rejection under 35 U.S.C. § 112, First Paragraph, enablement.

**V. Claim Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 1-14, 16 and 41-43 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly “being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” In particular, the PTO alleges that the rejected claims are indefinite or depend from a claim that is indefinite due to a number of minor informalities.

Claims 1-14, 16 and 41-43 have been canceled. The cancellation renders the rejection moot. New claims 49-65 comply with the requirement of 35 U.S.C. § 112, second paragraph.

**VI. Claim Rejections Under 35 U.S.C. § 102**

Claims 1, 9-10, 12-14, 16 and 41 are rejected under 35 U.S.C. § 102(e) as being anticipated by Kramer *et al.* (US 6,281,413), Jarrett *et al.* (WO 98/08388), and Grkovic *et al.* (1995, Appl. Environ. Microbiol. 61:2218-2223).

In particular, the PTO alleges that Kramer *et al.* disclose an isolated DNA insecticidal complex with 54% identity to SEQ ID NO: 1, while Jarrett *et al.* discloses a DNA sequence with 53.1% identity to SEQ ID NO: 1. The PTO further alleges that Kramer *et al.* and Jarrett *et al.* also show recombinant expression vectors transformed with this insecticidal complex, and Grkovic *et al.* discloses isolated PADAP DNA from *Serratia entomophila*. For the reasons outlined below, Applicants respectfully disagree.

Applicants submit that the cancellation of Claims 1, 9-10, 12-14, 16 and 41 renders the rejections to these claims moot.

New Claim 50 is directed to an isolated nucleic acid molecule comprising a nucleic acid sequence having at least 70% sequence identity to SEQ ID NO: 1 and wherein said nucleic acid molecule encodes a polypeptide that has the same insecticidal activity of a polypeptide encoded by SEQ ID NO:1. Krammer and Jarrett do not disclose sequences that are 70% identical to SEQ ID NO: 1 as claimed in Claim 50 because their sequences only share 54% and 53.1% identity with SEQ ID NO:1.

New Claim 51 is directed to a fragment of the isolated nucleic acid molecule of Claim 49, wherein the encoded protein of said fragment has insecticidal activity. New Claim 49 is directed to an isolated nucleic acid molecule comprising a nucleotide sequence of SEQ ID NO: 1.

The longest common fragment shared by SEQ ID NO: 1 and the sequence in Krammer (or Jarrett) is only about 20-30 nucleotides in length, which encodes a polypeptide fragment of about 6-10 amino acids in length. Such a short polypeptide fragment cannot possibly have the insecticidal activity of the polypeptide encoded by SEQ ID NO:1, which is at least a few hundred amino acid long. Therefore, Krammer and Jarrett do not anticipate the fragments claimed in Claim 51.

New Claim 58 is directed to an isolated nucleic acid molecule having at least 70% sequence identity with the sequence of the isolated nucleic acid molecule of Claim 52, 53, or 54. Claims 52 is directed to an isolated nucleic acid molecule comprising one or more of the nucleotide sequences 2411-9547, 9589-13883 or 14546-17467 of SEQ ID NO: 1. Claim 53 is directed to the isolated nucleic acid molecule of Claim 52, comprising all of nucleotide sequences 2411-9547, 9598-13884 and 14546-17467 of SEQ ID NO: 1. Claims 54 is directed to the isolated nucleic acid molecule of Claim 53, comprising the nucleotide sequence 1995-18937 of SEQ ID NO: 1.

As the sequence alignment report provided by the PTO does not indicate that Krammer or Jarrett discloses a nucleic acid sequence that share 70% sequence identity with the claimed fragment, Applicants respectfully submit that Krammer and Jarrett do not anticipate Claim 59.

Grkovic discloses an incomplete plasmid clone with only one partial disease conferring region as described on page 25 in the specification. Further, Grkovic did not disclose any sequence data, including SEQ ID NO:1 or fragments thereof. Therefore, Applicants respectfully submit that Grkovic does not anticipate Claims 50, 51 and 59.

The PTO is therefore requested to reconsider and withdraw the rejection under 35 U.S.C. § 102.

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**CONCLUSION**

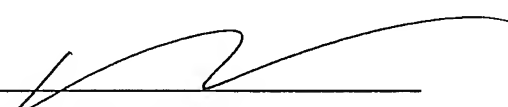
In view of the above amendments and remarks, allowance of the application is respectfully requested.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 08-1641 (Docket No. 24747-1104).

Respectfully submitted,

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